Complete Summary

GUIDELINE TITLE

Refractive errors and refractive surgery.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Ophthalmology Refractive Management/Intervention Panel. Refractive errors & refractive surgery. San Francisco (CA): American Academy of Ophthalmology; 2007. 70 p. [469 references]

GUIDELINE STATUS

This is the current release of the guideline.

It updates a previous version: American Academy of Ophthalmology Refractive Errors Panel. Refractive errors. San Francisco (CA): American Academy of Ophthalmology; 2002. 53 p. [297 references]

All Preferred Practice Patterns are reviewed by their parent panel annually or earlier if developments warrant and updated accordingly. To ensure that all Preferred Practice Patterns are current, each is valid for 5 years from the "approved by" date unless superseded by a revision.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Refractive errors, including hyperopia, myopia, astigmatism, and presbyopia

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Treatment

CLINICAL SPECIALTY

Ophthalmology
Optometry

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To improve the visual acuity, visual function, and visual comfort in patients with a refractive error by correcting the refractive error when appropriate, by addressing the following goals:

- Determine the patient's visual needs
- Identify and quantify any refractive errors
- Discuss with the patient the nature of the refractive error, appropriate alternatives for correction, and the risks and benefits of each approach
- Inform patients, especially those with high refractive errors, about the potentially increased incidence of associated pathologic conditions
- Correct symptomatic refractive errors with spectacles, contact lenses, or surgery as desired by the informed patient and as deemed appropriate by the physician
- Provide the patient with follow-up care and management of any side effects or complications resulting from the correction provided

TARGET POPULATION

Individuals who are beyond the amblyogenic age and have refractive errors

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. History
2. Examination, including acuity measurement and refraction testing

Management

1. Eyeglasses
2. Contact lenses, including soft hydrogel, rigid gas-permeable, or silicone hydrogel lenses
3. Keratorefractive surgery
4. Intraocular refractive surgery

5. Counseling and referral

MAJOR OUTCOMES CONSIDERED

- Visual function (visual acuity) following correction of refractive errors
- Visual comfort and patient satisfaction following correction of refractive errors
- Complications of contact lenses and refractive surgery

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

In the process of revising this document, a detailed literature search in Medline and the Cochrane Library for articles in the English language was conducted on the subject of refractive error and refractive surgery for the years 2001 to September 2006.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Strength of Evidence Ratings

Level I: Includes evidence obtained from at least one properly conducted, well-designed randomized controlled trial. It could include meta-analyses of randomized controlled trials.

Level II: Includes evidence obtained from the following:

- Well-designed controlled trials without randomization
- Well-designed cohort or case-control analytic studies, preferably from more than one center
- Multiple-time series with or without the intervention

Level III: Includes evidence obtained from one of the following:

- Descriptive studies
- Case reports

- Reports of expert committees/organization (e.g., Preferred Practice Patterns [PPP] panel consensus with external peer review)

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The results of a literature search on the subject of refractive errors were reviewed by the Refractive Management/Intervention Panel and used to prepare the recommendations, which they rated in two ways. The panel first rated each recommendation according to its importance to the care process. This "importance to the care process" rating represents care that the panel thought would improve the quality of the patient´s care in a meaningful way. The panel also rated each recommendation on the strength of the evidence in the available literature to support the recommendation made.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Ratings of Importance to Care Process

Level A, defined as most important

Level B, defined as moderately important

Level C, defined as relevant, but not critical

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

These guidelines were reviewed by Council and approved by the Board of Trustees of the American Academy of Ophthalmology (September 8, 2007).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Ratings of importance to the care process (A-C) and ratings of strength of evidence (I-III) are defined at the end of the "Major Recommendations" field.

Diagnosis

The evaluation of refractive errors requires an assessment of both the refractive status of the eye, the patient's current mode of correction, symptoms, and visual needs. [A:III]

History

The history should incorporate the elements of the comprehensive adult medical eye evaluation in order to consider the patient's visual needs and any ocular pathology [A:III]

Examination

Distance visual acuity should be measured separately for each eye with current correction. [A:III]

The refraction of each eye should be evaluated independently, either objectively by retinoscopy, with an autorefractor, or with a wavefront analyzer; or it may be done subjectively. [A:III] In cooperative patients, subjective refinement of refraction using a phorometer or trial lens set is preferred. [B:III] Distance refraction should be performed with accommodation relaxed. [B:III] Near vision should be measured in each eye before cycloplegia for patients with high hyperopia, presbyopia, or complaints about near vision. [B:III]

Management

Eyeglasses

Patients with low refractive errors may not require correction; small changes in refractive corrections in asymptomatic patients are generally not recommended. [A:III] Eyeglasses are the simplest and safest means of correcting a refractive error; therefore eyeglasses should be considered before contact lenses or refractive surgery. [A:III] A patient's eyeglasses and refraction should be evaluated whenever visual symptoms develop. [A:III]

Safety glasses or eye protectors are strongly recommended for individuals involved in certain sports (e.g., racquetball, squash) and hazardous activities in which there is risk of flying particles (e.g., using hammers, saws, weed trimmers) (American Academy of Pediatrics and American Academy of Ophthalmology, 2003) [A:III] They are also recommended for all individuals with good vision in only one eye. [A:III] When ocular protection is the foremost consideration,

polycarbonate plastic is the material of choice, because it is much more impact resistant than regular plastic or hardened glass (Vinger et al., 1997) [A:I]

Contact Lenses

Before contact lens fitting, an ocular history including past contact lens experience should be obtained and a comprehensive medical eye evaluation should be performed (see the National Guideline Clearinghouse [NGC] summaries of the American Academy of Ophthalmology [AAO] Preferred Practice Patterns Comprehensive adult medical eye evaluation and Pediatric eye evaluations: I. Screening. II. Comprehensive ophthalmic evaluation). [A:III] Patients should be made aware that using contact lenses can be associated with the development of ocular problems, including microbial corneal ulcers that may be vision threatening, and that overnight wear of contact lenses is associated with an increased risk of ulcerative keratitis (Mondino et al., 1986; Poggio et al., 1989; Stehr-Green et al., 1987) [A:II] The increased risk of ulcerative keratitis with extended contact lens wear should be discussed with patients who are considering this modality of vision correction (Poggio et al., 1989) [A:I] Before being fitted with overnight wear contact lenses, patients should be informed of their responsibilities and the increased risks of overnight wear compared with daily wear.[A:III]

The United States Food and Drug Administration has made the following recommendations for contact lens wearers regarding proper lens care practices (U.S. Food and Drug Administration, 2007) [A:III]

- Wash hands with soap and water, and dry (lint-free method) before handling contact lenses.
- Wear and replace contact lenses according to the schedule prescribed by the doctor.
- Follow the specific contact lens cleaning and storage guidelines from the doctor and the solution manufacturer.
- Keep the contact lens case clean and replace every 3 to 6 months.
- Remove the contact lenses and consult your doctor immediately if you experience symptoms such as redness, pain, tearing, increased light sensitivity, blurry vision, discharge, or swelling.

First-time daily-wear or extended-wear contact lens users should be checked soon after the contact lenses are initially dispensed. [A:III] Experienced contact lens users should generally be examined annually. [A:III]

Keratorefractive Surgery

Preoperative Evaluation

A comprehensive medical eye evaluation should be performed before any refractive surgery procedure. [A:III] In addition to the elements listed in the comprehensive adult medical eye evaluation (see the NGC summary of the AAO Preferred Practice Pattern Comprehensive adult medical eye evaluation), the refractive surgery examination should also include the following elements: [A:III]

- Visual acuity without correction

- Manifest, and where appropriate, cycloplegic refraction
- Computerized corneal topography
- Central corneal thickness measurement
- Evaluation of tear film
- Evaluation of ocular motility and alignment (Snir et al., 2003)

The patient should be informed of the potential risks, benefits, and alternatives to and among the different refractive procedures before surgery. [A:III] The informed consent process should be documented, and the patient should be given an opportunity to have all questions answered before surgery. [A:III]

Refer to the original guideline document for detailed management recommendations.

Postoperative Care

Postoperative management is integral to the outcome of any surgical procedure and is the responsibility of the operating surgeon (American Academy of Ophthalmology and American Society of Cataract and Refractive Surgery, 2000; American Academy of Ophthalmology, 2006) [A:III]

For patients undergoing refractive surgery with surface ablation techniques, postoperative examination, including slit-lamp biomicroscopy of the cornea, is advisable on the day following surgery and every 2 to 3 days thereafter until the epithelium is healed. [A:III]

For patients who have had uncomplicated laser in situ keratomileusis (LASIK) surgery, postoperative examination should be performed within 48 hours following surgery, a second visit should be performed 1 to 4 weeks postoperatively, and further visits thereafter as appropriate. [A:III]

Intraocular Refractive Surgery

Preoperative Evaluation

A comprehensive medical eye evaluation should be performed before any refractive surgery procedure. [A:III] In addition to the elements listed in the comprehensive adult medical eye evaluation (see the NGC summary of the AAO Preferred Practice Pattern Comprehensive adult medical eye evaluation), the intraocular refractive surgery examination includes the following elements in the table below.

Achieving the targeted postoperative refraction for refractive lens exchange requires measuring axial length accurately, determining corneal power, and using the most appropriate intraocular power formula for that eye. [A:III]

Table. Elements of the Intraocular Refractive Surgery Preoperative Evaluation [A:III]

Element	Phakic Intraocular Lens (IOL) Implantation	Refractive Lens Exchange
Computerized corneal topography	Optional	Yes
Central corneal thickness measurement	Yes	Optional
Axial length	Optional*	Yes
White-to-white measurement of the limbus	Yes	Optional
Specular microscopy/confocal microscopy	Yes	Optional
Anterior chamber depth	Yes	Yes
Pupil size	Yes	Yes

* The surgeon should be prepared to implant a pseudophakic IOL in the case that there is significant damage to the lens during phakic lens implantation.

Refer to the original guideline document for detailed management recommendations.

Postoperative Care

Components of each postoperative examination should include: [A:III]

- Interval history, including use of postoperative medications, new symptoms, and self-assessment of vision
- Measurement of visual function (e.g., visual acuity, pinhole testing)
- Measurement of intraocular pressure
- Slit-lamp biomicroscopy
- Counseling/education
- Management plan

Provider

Patients with refractive errors should be examined and evaluated for treatment by an ophthalmologist or an optometrist. [A:III] Surgical treatment of refractive

errors, including excimer laser surgery, should be performed only by an appropriately trained ophthalmologist. [A:III]

Counseling/Referral

Any decisions about surgical correction of a refractive error should be made by an informed patient and an ophthalmologist familiar with refractive surgery. [A:III] Information and discussion about the planned procedure should be available sufficiently in advance of the proposed surgical date so that the patient can carefully consider the risks, benefits, and alternatives to the procedure. [A:III]

Definitions:

Rating of Importance to the Care Process

Level A, defined as most important

Level B, defined as moderately important

Level C, defined as relevant but not critical

Rating of Strength of Evidence

Level I: Includes evidence obtained from at least one properly conducted, well-designed randomized controlled trial. It could include meta-analyses of randomized controlled trials.

Level II: Includes evidence obtained from the following:

- Well-designed controlled trials without randomization
- Well-designed cohort or case-control analytic studies, preferably from more than one center
- Multiple-time series with or without the intervention

Level III: Includes evidence obtained from one of the following:

- Descriptive studies
- Case reports
- Reports of expert committees/organization (e.g., Preferred Practice Patterns [PPP] Panel consensus with external peer review)

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

The major reasons for treating refractive errors are to improve a patient's visual acuity, visual function, and visual comfort. It may be desirable to correct a very small error in one patient, while another may function well with no ill effects when the refractive error is not corrected. Other reasons for treatment include enhancing binocular vision (e.g., for driver safety) and controlling strabismus (e.g., accommodative esotropia).

POTENTIAL HARMS

- *Complications of contact lens use*: The most serious risk of contact lens use is the development of microbial keratitis, which can lead to visual loss even if properly treated. Other complications include tarsal papillary conjunctivitis, bulbar conjunctival changes, epithelial keratopathy, corneal neovascularization, nonmicrobial corneal infiltrates, and corneal warpage. Endothelial changes can also occur, including polymegathism, pleomorphism, and, rarely, reduction of endothelial cell density. While transient stromal edema frequently occurs, progressive corneal thinning of the epithelium and stroma during contact lens wear has also been reported.
- Refer to the original guideline document for a detailed listing and discussion of complications of refractive surgical procedures, including radial keratotomy, photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK), intrastromal corneal ring segment procedure, refractive lens exchange, phakic intraocular lens implantation, automated lamellar keratoplasty, epikeratoplasty, photorefractive keratectomy for hyperopia (H-PRK), thermal keratoplasty--noncontact technique, thermal keratoplasty—conductive keratoplasty, astigmatic keratotomy, and intraocular refractive surgery.
- *Monovision*: Caution should be used in considering monovision in patients who have had previous strabismus surgery, phorias, or intermittent tropias, as these patients may develop diplopia postoperatively.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contact Lens: Relative Contraindications

The use of contact lenses to correct refractive errors may not be advisable when there are significant eyelid, tear film, or ocular surface abnormalities related to keratoconjunctivitis sicca, blepharoconjunctivitis, acne rosacea, conjunctival cicatrization, corneal exposure, neurotrophic keratitis, or other corneal abnormalities. Other relative contraindications include use of topical steroids,

inflammation of the anterior segment, presence of a filtering bleb, poor hygiene, certain environmental or work settings (e.g., dust, volatile chemicals), a history of contact-lens-related corneal complications, limited dexterity, or inability to understand the risks and responsibilities involved.

Keratorefractive Surgery Contraindications

- Unstable refraction
- Certain abnormalities of the cornea (e.g., keratoconus or other corneal ectasias, thinning, edema, interstitial or neurotrophic keratitis, extensive vascularization)
- Insufficient corneal thickness for the proposed ablation depth
- Visually significant cataract
- Uncontrolled glaucoma
- Uncontrolled external disease (e.g., blepharitis, dry eye syndrome, atopy/allergy)
- Uncontrolled connective tissue or autoimmune disease
- Unrealistic patient expectations

Keratorefractive Surgery: Relative Contraindications

- Functional monocularity
- Ocular conditions that limit visual function
- Excessively steep or flat corneas
- Abnormal corneal topography suggestive of forme fruste of keratoconus, keratoconus, or other corneal ectasias
- Significant irregular astigmatism
- Corneal stromal or endothelial dystrophies
- History of herpes simplex virus or varicella zoster virus keratitis
- Significant dry eye syndrome
- Prior incisional or lamellar keratorefractive surgery
- Glaucoma
- Diabetes mellitus
- Pregnancy or lactation
- Connective tissue or autoimmune diseases
- Certain systemic medications (e.g., isotretinoin, amiodarone, sumatriptan, levonorgestrel implants, colchicine)
- Under 21 years of age (U.S. Food and Drug Administration [FDA] labeling should be consulted for each laser)

Intraocular Refractive Surgery: Relative Contraindications

- Unstable refraction
- Visually significant cataract in the case of phakic intraocular lens (IOL)
- Corneal endothelial disease, including Fuchs dystrophy
- Uncontrolled glaucoma
- Uncontrolled external disease
- Uncontrolled connective tissue or autoimmune disease
- Unrealistic patient expectations

Intraocular Refractive Surgery: Relative Contraindications

The use of intraocular refractive surgery to correct refractive errors may not be advisable when there are preexisting systemic or ocular conditions that may increase the relative risk of intraocular surgery.

- Significant eyelid, tear film, or ocular surface abnormalities related to keratoconjunctivitis sicca, blepharoconjunctivitis, acne rosacea, conjunctival cicatrization, corneal exposure, neurotrophic keratitis, or other corneal abnormalities
- Inflammation of the anterior segment
- Presence of a filtering bleb
- Functional monocularity
- Connective tissue or autoimmune disease
- Diabetes mellitus
- Pregnancy or lactation
- History of uveitis

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- **Preferred Practice Patterns provide guidance for the pattern of practice, not for the care of a particular individual.** While they should generally meet the needs of most patients, they cannot possibly best meet the needs of all patients. Adherence to these *Preferred Practice Patterns* will not ensure a successful outcome in every situation. These practice patterns should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the best results. It may be necessary to approach different patients´ needs in different ways. The physician must make the ultimate judgment about the propriety of the care of a particular patient in light of all of the circumstances presented by that patient. The American Academy of Ophthalmology is available to assist members in resolving ethical dilemmas that arise in the course of ophthalmic practice.
- **Preferred Practice Patterns are not medical standards to be adhered to in all individual situations.** The Academy specifically disclaims any and all liability for injury or other damages of any kind, from negligence or otherwise, for any and all claims that may arise out of the use of any recommendations or other information contained herein.
- References to certain drugs, instruments, and other products are made for illustrative purposes only and are not intended to constitute an endorsement of such. Such material may include information on applications that are not considered community standard, that reflect indications not included in approved Food and Drug Administration (FDA) labeling, or that are approved for use only in restricted research settings. The FDA has stated that it is the responsibility of the physician to determine the FDA status of each drug or device he or she wishes to use, and to use them with appropriate patient consent in compliance with applicable law.
- Treatments have been reported that purport to prevent progression of refractive errors, particularly myopia. Evidence reported in the peer-reviewed literature, including recent randomized clinical trials, is currently insufficient to support a recommendation for intervention (see Appendix 3 of the original guideline document).

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Academy of Ophthalmology Refractive Management/Intervention Panel. Refractive errors & refractive surgery. San Francisco (CA): American Academy of Ophthalmology; 2007. 70 p. [469 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 Sep (revised 2007 Sep)

GUIDELINE DEVELOPER(S)

American Academy of Ophthalmology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Ophthalmology without commercial support

GUIDELINE COMMITTEE

Refractive Management/Intervention Panel; Preferred Practice Patterns Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Members of the Refractive Management/Intervention Panel: Stephen D. McLeod, MD, Chair; Roy S. Chuck, MD, PhD; D. Rex Hamilton, MD; James A. Katz, MD; Srilata S. Naidu, MD, Contact Lens Association of Ophthalmologists Representative; Allan R. Rutzen, MD, FACS; John A. Vukich, MD, American Society of Cataract and Refractive Surgery Representative; Susan Vitale, PhD, MHS, Methodologist

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

These authors have disclosed the following financial relationships occurring from January 2006 to August 2007:

Stephen D. McLeod, MD: Alcon Laboratories, Inc. – Consultant/Advisor, Lecture fees, Grant support; Insite Vision, Inc. – Consultant/Advisor; Visiogen, Inc. – Consultant/Advisor, Lecture fees, Equity owner, Grant support.

Roy S. Chuck, MD: Alcon Laboratories, Inc., Allergan, Inc., IOP, Ista Pharmaceuticals – Lecture fees; WMR Biomedical – Consultant/Advisor.

John A. Vukich MD: AcuFocus, Inc., Lenstec, Inc. – Grant support; Advanced Medical Optics, STAAR Surgical Co., Visiogen, Inc. – Consultant/Advisor; Carl Zeiss Meditec – Lecture fees.

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GUIDELINE AVAILABILITY

Electronic copies: Available from the American Academy of Ophthalmology (AAO) Web site.

Print copies: Available from American Academy of Ophthalmology, P.O. Box 7424, San Francisco, CA 94120-7424; telephone, (415) 561-8540.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Summary benchmarks for preferred practice patterns. San Francisco (CA): American Academy of Ophthalmology; 2007 Nov. 22 p.

Available in Portable Document Format (PDF) and as a Personal Digital Assistant (PDA) download from the American Academy of Ophthalmology (AAO) Web site.

Print copies: Available from American Academy of Ophthalmology, P.O. Box 7424, San Francisco, CA 94120-7424; telephone, (415) 561-8540.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on December 1, 1998. The information was verified by the guideline developer on January 11, 1999. This summary was updated on March 12, 2003. The updated information was verified by the guideline developer on April 2, 2003. This NGC summary was updated by ECRI Institute on February 6, 2008. The updated information was verified by the guideline developer on February 27, 2008.

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Date Modified: 9/29/2008